Hamza M, White PF, et al. Percutaneous Electrical Nerve Stimulation [PENS]. Diabetes Care 2000;23(3):365-370.

Design: Randomized crossover trial

Population/sample size/setting:

- 50 patients with Type 2 diabetes (28 women, 22 men, mean age 55) treated for neuropathic pain at a university anesthesiology department in Dallas
- Eligible if they had painful neuropathic symptoms in both lower extremities for more than 6 months, with abnormal nerve conduction studies confirming the diagnosis of peripheral neuropathy
- Exclusion criteria were pregnancy, cardiac arrhythmias, infection/gangrene, history of vascular insufficiency in legs, drug/alcohol abuse, psychiatric disease, major organ disease, radicular pain, and treatment with steroids, phenytoin, or chemotherapeutic agents

Main outcome measures:

- All participants received both active PENS and sham PENS, and the order was randomized, either active-sham (n=25) or sham-active (n=25)
- Both active and sham PENS involved the placement of ten 32-gauge stainless steel acupuncture-like needle probes 1-3 cm into the soft tissues of both legs and both feet, targeting the tibial and deep peroneal nerves, connected to a low-output electrical generator, with sessions three times per week for three weeks
- A one-week washout period was interposed between the two treatment periods
- Active PENS probes were stimulated at alternating frequencies of 15 and 30 Hz every 3 seconds; sham PENS was stimulated at 0 Hz
- Physical component Summary (PCS) and Mental Component Summary (MCS) of the SF-36 was completed at baseline and again 48 hours after completion of the first three week period and the second three week period
- Beck Depression Inventory (BDI) and Profile of Mood Status (POMS) were completed at the same time as the PCS and MCS
- Baseline levels of pain, physical activity, and sleep quality were recorded on 3 separate VAS (0-10) before each treatment session, after each week of treatment, and again at the end of each three-week period of treatment
- Daily diaries were kept to record analgesic usage
- 24 hours after the final treatment session, patients completed a questionnaire asking them to compare the relative effectiveness of the two interventions they had received
- Pain VAS improved during active PENS but not during sham PENS treatment
    - Participants who received active PENS first decreased their average pain scores from 6.2 to 2.5 at week 3; the group which received sham PENS first had baseline mean pain of 6.4 and 6.3 at the same time points
    - Participants who received active PENS after sham PENS decreased their average pain scores from 6.2 to 2.6; participants who receive

sham PENS after active PENS went from a mean baseline score of 5.2 to a mean score of 4.8 after 3 weeks of sham PENS

- Activity and sleep scores, as well as SF-36 subscale scores, showed an advantage of active over sham PENS
- Daily analgesic use decreased over the course of the 21 days of active PENS treatment, but not during sham PENS

Authors' conclusions:

- PENS produces short-term pain relief, sleep quality, and mood improvement
- The symptom scores began to return to baseline values after the one-week washout period, suggesting that the effects of PENS are transient
- This transient effect would necessitate a maintenance program of treatment if PENS is to have a lasting effect
- Patient bias may have arisen because they could not be blinded to the electrical sensation from active PENS
- PENS should be viewed as a supplementary therapy rather than an alternative to conventional pharmacological therapy for diabetic neuropathic pain

Comments:

- Many of the problems with PENS are discussed by the authors, especially the abatement of its effects after one week of washout
- There may have been a small carryover effect of active PENS, but in each of the treatment periods, the effect of active PENS appears to be approximately equal, so that a period effect is likely to be small and not likely to obscure a treatment effect
- While a small carryover effect is advantageous for interpreting crossover studies, it is also evidence that the effects of the intervention are short-lasting, which can influence decisions concerning their suitability in a chronic pain setting
- It is not clear from the text just what the improvements were in the SF-36 subscale scores, since the pre-treatment and post-treatment mean scores are not supplied

Assessment; Adequate for evidence that active PENS is more effective than sham PENS in treating diabetic neuropathic pain, and adequate for evidence that the effect of PENS is transient, probably making a maintenance treatment necessary